



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

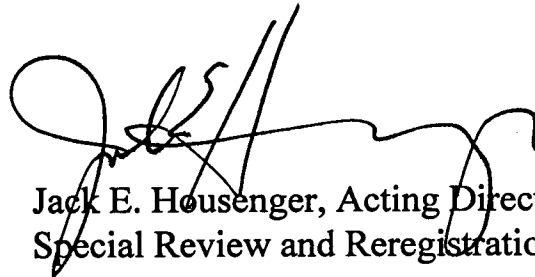
The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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June 1, 1999

MEMORANDUM

SUBJECT: Acute and Chronic Dietary Exposure and Risk Analysis for Coumaphos (PC code 036501); DP Barcode D256125; Submission S561774; Case 818804.

FROM: Christina Jarvis, EPS
Sherrie L. Mason, Chemist
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

And

Susie Chun, Chemist
Dave Soderberg, Chemist
Dietary Exposure Science Advisory Council
Health Effects Division (7509C)

TO: Christina Jarvis, Risk Assessor
Reregistration Branch II
Health Effects Division (7509C)

Action Requested

An acute and chronic dietary exposure assessment was requested to determine the risks associated with the reregistration of coumaphos. There are no registered uses of coumaphos on food crops; however, tolerances exist for residues in meat and milk.

Executive Summary

A Tier II acute and chronic dietary exposure assessment was conducted for the organophosphorus insecticide coumaphos, to determine the risks associated with uses of coumaphos for the control of arthropod pests on cattle, goats, horses, sheep, and swine. Anticipated residues are utilized to estimate the dietary exposure to coumaphos in the diets of the U.S. population, as well as certain sub-populations. No refinement to percent livestock treated information is incorporated into this assessment.

Acute risks associated with the use of coumaphos do not exceed HED's level of concern (>100% PAD¹). The acute dietary risk is 31% of the acute PAD for the most highly exposed sub-population, children 1-6. Chronic dietary risks associated with the use of coumaphos do exceed HED's level of concern (>100% PAD) for the most highly exposed sub-population (children 1-6) only. The chronic dietary risk for children 1-6 is 106% of the chronic PAD.

Because the chronic risk to children 1-6 is marginal, additional data (i.e. cooking and processing studies; percent livestock treated information) would help further refine the risk.

Toxicological Information

On May 11, 1999, the Hazard Identification Assessment Review Committee (HIARC) met to discuss acute and chronic hazard endpoint selection for dietary exposure to coumaphos. Prior to this meeting, Bayer Corporation had submitted acute and subchronic neurotoxicity studies in the rat; these studies have been reviewed and are found to be acceptable. The registrant has satisfied all requirements for acute and subchronic neurotoxicity studies in the rat. Therefore, the HIARC recommended to the FQPA Safety Factor Committee that the FQPA factor be removed in assessing the risk posed by coumaphos (N. Paquette memo, 5/12/99). In a meeting on May 17, 1999, the FQPA Safety Factor Committee accepted this recommendation, and the FQPA safety factor was removed (B. Tarplee memo, 06/01/99). Since the FQPA safety factor was removed (i.e., reduced to 1X), the acute and chronic PADs are the same values as their respective RfDs.

The toxicology database for coumaphos is complete, and will support reregistration. Coumaphos is a Group E chemical, indicating that it is not likely to be carcinogenic in humans via relevant routes of exposure. This classification is based on adequate studies in two animal species.

The following toxicology endpoints are used in the acute and chronic dietary risk assessment:

¹ PAD = Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

Table 1: Doses and Endpoints Selected for Acute and Chronic Dietary Risk Assessment

	Acute	Chronic
Critical Study	Acute Neurotoxicity Study in the Rat (MRID 44544801)	1-Year Dog Feeding Study (MRID 43055301)
Endpoint	RBC ChEI²	Plasma, RBC ChEI
NOAEL	2.0 mg/kg (LOAEL) NOAEL not achieved in males	0.025 mg/kg/day
Uncertainty Factor	UF= 300 100X inter- and intraspecies variation and 3X lack of NOAEL	UF=100 100X inter- and intraspecies variation
RfD	0.007 mg/kg	0.00025 mg/kg/day
FQPA Safety Factor	Reduced to 1X (FQPA factor removed)	Reduced to 1X (FQPA factor removed)
PAD	0.007 mg/kg (Same as acute RfD)	0.00025 mg/kg/day (Same as chronic RfD)

Residue Information

The published tolerances for coumaphos are listed in 40 CFR §180.189. Tolerances are listed for:

Meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry and sheep **1.0 ppm**
Milk-fat residues, reflecting negligible residues in milk **0.5 ppm**
Eggs **0.1 ppm**

No changes to the milk, sheep, cattle, horse, goat, and hog tolerances are required. Although tolerances are still listed for poultry and eggs, the use of coumaphos on poultry (eggs) has been canceled. The acute and chronic Dietary Exposure Evaluation Model (DEEM™) analyses use the following anticipated residue values, calculated in a memo by M. Metzger, dated 7/18/89. The anticipated residue values are still considered appropriate for dietary risk assessment purposes. The chronic anticipated residue for beef fat has been revised to 0.072 ppm from 0.15 ppm (C. Olinger memo, 3/7/95).

Table 2: Anticipated Residue Values for Use in Calculating Acute and Chronic Exposure

Commodity	Anticipated Residue (ppm)	
	Chronic	Acute
Beef (and horse), lean meat without removable fat	0.03	0.05
Beef, fat	0.072	0.40

² ChEI = Cholinesterase Inhibition

Commodity	Anticipated Residue (ppm)	
	Chronic	Acute
Beef, liver (and meat by-products)	0.10	0.10
Beef, kidney	0.04	0.04
Goat, lean meat without removable fat	0.04	0.20
Goat, fat	0.50	1.0
Goat, liver (and meat by-products)	0.03	0.03
Goat, kidney	0.02	0.03
Hog, lean meat	0.03	0.20
Hog, fat	0.06	0.60
Hog, liver (and meat by-products)	0.02	0.02
Hog, kidney	0.02	0.02
Sheep, lean meat without removable fat	0.05	0.25
Sheep, fat	0.50	1.0
Sheep, liver (and meat by-products)	0.03	0.08
Sheep, kidney	0.04	0.09
Milk	0.006	0.02

No refinements using percent livestock treated information have been incorporated into the dietary exposure analysis for acute or chronic risk. The DEEM™ default concentration factors were used in both the acute and chronic analyses.

Results and Discussion

The acute and chronic dietary exposure assessments were performed using DEEM™. DEEM™ is used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. The software contains food consumption data from the U.S. Department of Agriculture Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992. A summary of the residue information used in the acute and chronic analyses is attached (Attachments 1 and 3).

Acute Exposure Analysis: (Tier 2)

The detailed acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups. The analysis evaluates exposure to coumaphos for each food commodity and assumes uniform distribution of coumaphos in the food

supply. The results of the acute dietary analysis are attached (Attachment 2).

Table 3: Acute Dietary Risk Estimates

Population	Exposure	% Acute PAD (95th Percentile)
U.S. Population	0.001187	17%
All Infants (<1 year)	0.001813	26%
Children 1-6 years	0.002189	31%
Females 13+/nursing	0.000949	14%
Males 13-19	0.000961	14%

Chronic Exposure Analysis: (Tier 2)

A chronic exposure analysis for coumaphos was performed utilizing the DEEMTM exposure modeling software. The input values include the anticipated residues for commodities on which coumaphos is used. The results of the chronic dietary analysis are attached (Attachment 4).

Table 4: Chronic Dietary Risk Estimates

Population	Exposure	% Chronic PAD
U.S. Population	0.000098	39%
All Infants (<1 year)	0.000093	37%
Children 1-6 years	0.000266	106%
Females 13-19 (not pregnant, non-nursing)	0.000086	35%
Males 13-19	0.000110	44%

Conclusions

For the acute dietary exposure analysis of coumaphos, exposure (residue x consumption) was compared to an acute population adjusted dose of 0.007 mg/kg/day, which reflects an FQPA factor of 1. At the 95th percentile, the acute dietary risks associated with the use of coumaphos do not exceed the HED's level of concern for any population subgroup. The acute dietary risk for the highest exposed sub-population (children 1-6) at the 95th percentile is 31% of the PAD. Pork contributes the greatest dietary burden to the acute risk for this subpopulation.

The chronic dietary risks associated with the use of coumaphos do not exceed HED's level of concern for any population subgroup, with the exception of children 1-6. The chronic dietary risk for children 1-6 is 106% of the PAD. Milk contributes the greatest dietary burden to the chronic risk for this subpopulation.

Because the chronic risk to children 1-6 is marginal and not highly refined, more data, such as cooking and processing studies and percent livestock treated information, would further refine the risk.

Attachments

Attachment 1: Residue Information (Acute)

Attachment 2: Results of Acute Dietary Exposure Analysis

Attachment 3: Residue Information (Chronic)

Attachment 4: Results of Chronic Dietary Exposure Analysis

ATTACHMENT 1

"Counaphos"

0

NEWN, 0.007

NOEL, 0

2

0

05-28-1999/11:14:22

999

318	50000DB,D,	0.02	1	100	0	"Milk-nonfat solids", ""
319	50000FA,D,	0.02	1	100	0	"Milk-fat solids", ""
320	50000SA,D,	0.02	1	100	0	"Milk sugar (lactose)", ""
321	53001BA,M,	0.1	1	100	0	"Beef-meat byproducts", ""
322	53001BB,M,	0.1	1	100	0	"Beef-other organ meats", ""
323	53001DA,M,	0.05	1.92	100	0	"Beef-dried", ""
324	53001FA,M,	0.4	1	100	0	"Beef-fat w/o bones", ""
325	53001KA,M,	0.04	1	100	0	"Beef-kidney", ""
326	53001LA,M,	0.1	1	100	0	"Beef-liver", ""
327	53001MA,M,	0.05	1	100	0	"Beef-lean (fat/free) w/o bones", ""
328	53002BA,M,	0.03	1	100	0	"Goat-meat byproducts", ""
329	53002BB,M,	0.03	1	100	0	"Goat-other organ meats", ""
330	53002FA,M,	1	1	100	0	"Goat-fat w/o bone", ""
331	53002KA,M,	0.03	1	100	0	"Goat-kidney", ""
332	53002LA,M,	0.03	1	100	0	"Goat-liver", ""
333	53002MA,M,	0.2	1	100	0	"Goat-lean (fat/free) w/o bone", ""
334	53003AA,M,	0.05	1	100	0	"Horsemeat", ""
336	53005BA,M,	0.08	1	100	0	"Sheep-meat byproducts", ""
337	53005BB,M,	0.08	1	100	0	"Sheep-other organ meats", ""
338	53005FA,M,	1	1	100	0	"Sheep-fat w/o bone", ""
339	53005KA,M,	0.09	1	100	0	"Sheep-kidney", ""
340	53005LA,M,	0.08	1	100	0	"Sheep-liver", ""
341	53005MA,M,	0.25	1	100	0	"Sheep-lean (fat free) w/o bone", ""
342	53006BA,M,	0.02	1	100	0	"Pork-meat byproducts", ""
343	53006BB,M,	0.02	1	100	0	"Pork-other organ meats", ""
344	53006FA,M,	0.6	1	100	0	"Pork-fat w/o bone", ""
345	53006KA,M,	0.02	1	100	0	"Pork-kidney", ""
346	53006LA,M,	0.02	1	100	0	"Pork-liver", ""
347	53006MA,M,	0.2	1	100	0	"Pork-lean (fat free) w/o bone", ""
398	50000WA,D,	0.02	1	100	0	"Milk-based water", ""
424	56000FA,M,	0.4	1	100	0	"Veal-fat w/o bones", ""
425	56000MA,M,	0.05	1	100	0	"Veal-lean (fat free) w/o bones", ""
426	56000KA,M,	0.04	1	100	0	"Veal-kidney", ""
427	56000LA,M,	0.1	1	100	0	"Veal-liver", ""
428	56000BB,M,	0.1	1	100	0	"Veal-other organ meats", ""
429	56000DA,M,	0.05	1.92	100	0	"Veal-dried", ""
430	56000BA,M,	0.1	1	100	0	"Veal-meat byproducts", ""

ATTACHMENT 2

U.S. Environmental Protection Agency

Ver. 6.78

DEEM ACUTE analysis for COUMAPHOS

(1989-92 data)

Residue file: 036501ac.R96

Adjustment factor #2 NOT used.

Analysis Date: 05-28-1999/11:16:44

Residue file dated: 05-28-1999/11:14:22/8

Acute Reference Dose (aRfD) = 0.007000 mg/kg body-wt/day

NOEL (Acute) = 2.000000 mg/kg body-wt/day

Summary calculations:

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. pop - all seasons:								
0.001187	16.96	1684	0.001976	28.22	1012	0.003397	48.54	588
All infants (<1 year):								
0.001813	25.91	1102	0.002970	42.42	673	0.003974	56.77	503
Children (1-6 years):								
0.002189	31.27	913	0.003272	46.74	611	0.004643	66.32	430
Children (7-12 years):								
0.001461	20.88	1368	0.002436	34.80	821	0.003255	46.49	614
Females (13+/preg/not nsg):								
0.000701	10.02	2852	0.001059	15.13	1888	0.001428	20.41	1400
Females (13+/nursing):								
0.000949	13.56	2107	0.001553	22.18	1288	0.001586	22.66	1261
Females (13-19 yrs/np/nn):								
0.000910	12.99	2198	0.001393	19.90	1435	0.001866	26.66	1071
Females (20+ years/np/nn):								
0.000657	9.39	3042	0.001062	15.18	1882	0.001696	24.23	1179
Females (13-50 years):								
0.000745	10.64	2686	0.001233	17.62	1621	0.001853	26.47	1079
Males (13-19 years):								
0.000961	13.73	2081	0.001475	21.07	1355	0.002740	39.14	729
Males (20+ years):								
0.000829	11.84	2413	0.001304	18.63	1533	0.002157	30.82	927
Seniors (55+):								
0.000654	9.34	3057	0.001039	14.85	1924	0.001602	22.89	1248

ATTACHMENT 3

"Coumaphos"
0.00025

NEWN, 0
NOEL, 0.025

05-12-1999/14:31:59

999

318	50000DB,D,	0.006	1	100	0	"Milk-nonfat solids", ""
319	50000FA,D,	0.006	1	100	0	"Milk-fat solids", ""
320	50000SA,D,	0.006	1	100	0	"Milk sugar (lactose)", ""
321	53001BA,M,	0.1	1	100	0	"Beef-meat byproducts", ""
322	53001BB,M,	0.1	1	100	0	"Beef-other organ meats", ""
323	53001DA,M,	0.03	1.92	100	0	"Beef-dried", ""
324	53001FA,M,	0.072	1	100	0	"Beef-fat w/o bones", ""
325	53001KA,M,	0.04	1	100	0	"Beef-kidney", ""
326	53001LA,M,	0.1	1	100	0	"Beef-liver", ""
327	53001MA,M,	0.03	1	100	0	"Beef-lean (fat/free) w/o bones", ""
328	53002BA,M,	0.03	1	100	0	"Goat-meat byproducts", ""
329	53002BB,M,	0.03	1	100	0	"Goat-other organ meats", ""
330	53002FA,M,	0.5	1	100	0	"Goat-fat w/o bone", ""
331	53002KA,M,	0.02	1	100	0	"Goat-kidney", ""
332	53002LA,M,	0.03	1	100	0	"Goat-liver", ""
333	53002MA,M,	0.04	1	100	0	"Goat-lean (fat/free) w/o bone", ""
334	53003AA,M,	0.03	1	100	0	"Horsemeat", ""
336	53005BA,M,	0.03	1	100	0	"Sheep-meat byproducts", ""
337	53005BB,M,	0.03	1	100	0	"Sheep-other organ meats", ""
338	53005FA,M,	0.5	1	100	0	"Sheep-fat w/o bone", ""
339	53005KA,M,	0.04	1	100	0	"Sheep-kidney", ""
340	53005LA,M,	0.03	1	100	0	"Sheep-liver", ""
341	53005MA,M,	0.05	1	100	0	"Sheep-lean (fat free) w/o bone", ""
342	53006BA,M,	0.02	1	100	0	"Pork-meat byproducts", ""
343	53006BB,M,	0.02	1	100	0	"Pork-other organ meats", ""
344	53006FA,M,	0.06	1	100	0	"Pork-fat w/o bone", ""
345	53006KA,M,	0.02	1	100	0	"Pork-kidney", ""
346	53006LA,M,	0.02	1	100	0	"Pork-liver", ""
347	53006MA,M,	0.03	1	100	0	"Pork-lean (fat free) w/o bone", ""
398	50000WA,D,	0.006	1	100	0	"Milk-based water", ""
424	56000FA,M,	0.072	1	100	0	"Veal-fat w/o bones", ""
425	56000MA,M,	0.03	1	100	0	"Veal-lean (fat free) w/o bones", ""
426	56000KA,M,	0.04	1	100	0	"Veal-kidney", ""
427	56000LA,M,	0.1	1	100	0	"Veal-liver", ""
428	56000BB,M,	0.1	1	100	0	"Veal-other organ meats", ""
429	56000DA,M,	0.03	1.92	100	0	"Veal-dried", ""
430	56000BA,M,	0.1	1	100	0	"Veal-meat byproducts", ""

ATTACHMENT 4

U.S. Environmental Protection Agency

Ver. 6.74

DEEM Chronic analysis for COUMAPHOS

(1989-92 data)

Residue file name: D:\RDF\036501cr.R96

Adjustment factor #2 NOT used.

Analysis Date 05-12-1999/14:34:18

Residue file dated: 05-12-1999/14:31:59/8

Reference dose (RfD, CHRONIC) = .00025 mg/kg bw/day

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000098	39.3%
U.S. Population (spring season)	0.000097	38.9%
U.S. Population (summer season)	0.000098	39.2%
U.S. Population (autumn season)	0.000100	40.1%
U.S. Population (winter season)	0.000097	39.0%
Northeast region	0.000095	38.2%
Midwest region	0.000108	43.1%
Southern region	0.000097	38.8%
Western region	0.000092	36.8%
Hispanics	0.000109	43.8%
Non-hispanic whites	0.000097	38.7%
Non-hispanic blacks	0.000098	39.3%
Non-hisp/non-white/non-black)	0.000105	42.1%
All infants (< 1 year)	0.000093	37.2%
Nursing infants	0.000030	11.8%
Non-nursing infants	0.000120	47.9%
Children 1-6 yrs	0.000266	106.4%
Children 7-12 yrs	0.000161	64.4%
Females 13-19(not preg or nursing)	0.000086	34.6%
Females 20+ (not preg or nursing)	0.000060	23.9%
Females 13-50 yrs	0.000067	26.7%
Females 13+ (preg/not nursing)	0.000084	33.5%
Females 13+ (nursing)	0.000078	31.2%
Males 13-19 yrs	0.000110	44.0%
Males 20+ yrs	0.000075	30.1%
Seniors 55+	0.000061	24.5%
Pacific Region	0.000090	36.0%
